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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/007,779

11/30/2001

Gerardo Castillo

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1128

7590

06/22/2006

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EXAMINER

BALLARD, KIMBERLY A

ART UNIT

PAPER NUMBER

1649

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/007,779

Applicant(s)

CASTILLO ET AL.

Examiner

Kimberly A. Ballard

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-10, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4, 10, 14 and 15 is/are rejected.
- 7) ☒ Claim(s) 6-9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application, Amendments and/or Claims

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 April 2006 has been entered.

Applicants' Amendment and Response filed 17 April 2006 has been entered. Claims 6 and 8 have been amended. Claims 4, 6-10, 14 and 15 are pending and under examination in the current office action.

The Examiner of U.S. Patent Application No. 10/007,779 has changed. In order to expedite the correlation of papers with the application, please direct all future correspondence to Examiner Ballard, Technology Center 1600, Art Unit 1649.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Claim Rejections

The rejection of claims 4, 6-10 and 14-15 under 35 U.S.C. 102(b) as being anticipated by Snow et al. as set forth at p. 3 ¶10 of the 10/17/05 office action is hereby *withdrawn* upon further consideration of Applicant's arguments.

The rejection of claims 6-9 under 35 U.S.C. 102(a) as being anticipated by Castillo et al. as set forth at p. 5 ¶11 of the 10/17/05 office action is hereby *withdrawn* upon further consideration.

Maintained Claim Rejections

The rejection of claims 4, 10, 14 and 15 under 35 U.S.C. 102(a) as being anticipated by Castillo et al. (*J Neurochem*, Dec 1997; **69**: 2452-2465) as set forth at p. 5 ¶11 of the 10/17/05 office action is maintained.

Applicant argues in the response filed 4/17/06 that Castillo 1997 reports on binding studies only, not on plaque formations, that Castillo reports that EHS perlecan could not be made to form plaques at all (Applicant indicates p. 2461, 2nd paragraph for support). Applicants distinguish that not everything that binds forms plaques, and not every plaque is the preferred Maltese cross plaque exhibiting a certain pattern when stained with Congo red and viewed under polarized light, and exhibiting an amyloid star appearance when viewed by transmission electron microscopy. Finally, Applicant argues that Castillo teaches away from the current claims.

Applicant's arguments have been fully considered but they are not persuasive. While Castillo may indeed report on binding assays, Castillo also describes A β fibril formation assays.

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The method steps utilized by Castillo, namely co-incubation of A β (1-40) with heparan sulfate glycosaminoglycans (HS GAGs; derived from EHS perlecan) in tris-buffered saline at pH 7.0 at 37°C for 2 weeks, wherein samples were taken at 1 day, 3 days, 1 week, and 2 weeks (see “Analysis of A β fibrillogenesis by thioflavin T fluorometry”, p. 2454-2455), are the same as those recited in instant claims 4, 10, 14, and 15. There is nothing in Applicant’s claimed method steps that would differentiate Applicant’s invention from the method steps disclosed by Castillo. Accordingly, although Castillo is silent with respect to formation of amyloid plaques displaying the characteristic Maltese cross formation and/or amyloid star appearance, there is nothing in the reference would otherwise teach that these plaque formations would not inherently occur.

Applicant’s referral to p. 2461 is perplexing as nowhere does the Examiner find a statement that perlecan could not be made to form plaques. In contrast, the same page notes, particularly at column 2, “[t]he use of perlecan from EHS tumor in the present study may actually have been an advantage due to its notably high N-sulfate content.” Moreover, the reference notes its inclusion as particularly stabilizing in plaque fibril formation and stability similar to that seen in Alzheimer’s brain. The reference at least provides suitably spherical/fibrillar plaques. Accordingly, the plaques are noted to be of the proper form as they were made via the same claimed procedure. Therefore, Castillo does not teach away from the claimed invention, and as such the rejection of claims 4, 10, 14 and 15 is maintained.

Allowable Subject Matter

Claims 6-9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 6-9 are objected to because of the following informalities: Claims 6-9 are dependent upon rejected claim 10.

Conclusion

Claims 6-9 are objected to, claims 4, 10, 14 and 15 are rejected.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Ballard whose telephone number is 571-272-4479. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kimberly Ballard, Ph.D.

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June 16, 2006


JANET L. ANDRES
SUPERVISORY PATENT EXAMINER